March 17, 2017

RE: Tribal Notification to Request Advice and Comments Letter 17-03: New Mexico Compliance with the federal Covered Outpatient Drug Rule

Dear Tribal Leadership, Indian Health Service, Tribal Health Providers, and Other Interested Parties:

Seeking advice and comments from New Mexico’s Indian nations, tribes, pueblos and their health care providers is an important component of the government-to-government relationship with the State of New Mexico. In accordance with the New Mexico Human Services Department’s (HSD’s) Tribal Notification to Request Advice and Comments process, this letter is to inform you that HSD, through the Medical Assistance Division (MAD), is accepting written comments until 5:00pm Mountain Standard Time (MST) on Wednesday, April 19, 2017, regarding changes in the reimbursement of pharmacy claims.

HSD is providing this notice for the purpose of receiving comment on proposed changes to pharmacy reimbursement to ensure that the New Mexico Medical Assistance Program payments comply with the federal Covered Outpatient Drug Rule. The federal Covered Outpatient Drug Rule (CODR) was published in the Federal Register on Monday, February 1, 2016 (Volume 81, No. 20) as a final rule to be included in 42 CFR Part 447 (refer to the web link, below).

The CODR specifies the maximum drug ingredient costs that may be paid on a pharmacy claim. HSD has prepared a draft State Plan Amendment that specifies that the allowed ingredient cost will be calculated as the lower of the National Average Drug Acquisition Cost (NADAC), the ingredient cost reported by the provider, or any other applicable federal upper limit. The draft State Plan Amendment also specifies that if there is not a NADAC amount, the Wholesale Acquisition Cost as reported by national drug pricing services will be used. The CODR also specifies that a provider is required to report the 340-B acquisition ingredient cost for any drug item purchased at 340-B prices. A provider who dispenses any drug item purchased through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340-B drug pricing program, must bill the actual acquisition cost as the ingredient cost of the drug item. These requirements are included in the draft State Plan Amendment.

Additionally, the CODR requires each state Medicaid agency to review their current dispensing fee. The rule redefines the dispensing fee as a Professional Dispensing Fee to cover other professional
services that the pharmacy may provide in addition to dispensing the drug item. In the draft State Plan Amendment, HSD is proposing a professional dispensing fee of $10.30 to be used in the calculations that determine a final payment to a pharmacy. This amount was developed after considering other state studies and proposed professional dispensing fees, and particularly the profession dispensing fees developed by neighboring states. New Mexico’s current dispensing fee is $3.65.

The draft State Plan Amendment includes federally required payment limitations on Medicaid-covered drug items purchased under federal government provisions. Specifically, a provider is required to report the actual acquisition ingredient cost for any drug item purchased at 340-B prices, the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8.

The draft State Plan Amendment also includes new wording to clarify that: (1) drug items that are for investigational use only are not covered under the New Mexico Medical Assistance program; (2) prior to dispensing controlled substances prescribed at amounts that exceed high codes limits, the pharmacy must verify the prescription with the prescriber (otherwise, the payment for the prescription may be subject to recoupment); and (3) dispensing of controlled substances that have not been reported as required to the New Mexico Board of Pharmacy Prescription Monitoring Program are subject to recoupment.

**Estimated Total Financial Impact and Impact on IHS and Tribal Healthcare Facilities**

The calculated financial impact is to the Medicaid fee-for-service (FFS) program.

- For all pharmacy providers, the impact of implementing a professional dispensing fee of $10.30 and the required changes to the ingredient cost calculations, a decrease in payment to pharmacy providers is anticipated to be $1.95 million annually in state and federal funds.

- Specifically for IHS and for tribal healthcare pharmacies, the anticipated annual increase in the professional dispensing fee is anticipated to be $613,000. This is approximately a 10 percent increase in payments to these pharmacies.

- For an IHS or tribal healthcare pharmacy that currently bills an ingredient cost on their pharmacy claims based on federal supply schedules or another discounted purchasing amount, it is not anticipated that there would be a significant change in the payment for ingredient costs on their pharmacy claims. For an IHS or tribal healthcare pharmacy that does not bill ingredient costs based on federal supply schedules or another discounted purchasing amounts, but begins to do so under this State Plan Amendment, it is estimated that there could be a 6 percent decrease in payments for the ingredient cost of the drug item.

**Other Tribal Impact**

In general, complying with the CMS Covered Outpatient Drug Rule will result in increased reimbursements to IHS and tribal healthcare pharmacies. However, there is specific wording in the rule that may change the reimbursement levels for these pharmacies with regard to payment for the cost of the ingredients in a drug item. It may also be necessary for these pharmacies to change how they bill
pharmacy claims with regard to ingredient costs, depending on how the pharmacies currently bill the Medicaid program. The Department would very much appreciate receiving comments on the following issues regarding reporting ingredient costs of drug items on the pharmacy claim form:

- The CODR specifies that a provider is required to report the 340-B acquisition ingredient cost for any drug item purchased at 340-B prices. A provider who dispenses any drug item purchased through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340-B drug pricing program must bill the actual acquisition cost as the ingredient cost of the drug item.

HSD/MAD’s understanding is that IHS and tribal healthcare pharmacy providers generally purchase drug items at the Federal Supply Schedule. If so, the pharmacy would be required to report the ingredient cost on the pharmacy claim. It is not known if IHS and tribal healthcare pharmacy providers currently state the ingredient cost on their claims, and if the amount is actually at the acquisition cost from their purchase source.

HSD is seeking information from tribal health care providers on the following questions:

a. Will this requirement require changes in how an IHS or tribal healthcare provider bills pharmacy claims?

b. Will this require IHS or tribal healthcare providers to make technical system changes?

c. Do IHS and tribal healthcare pharmacies need more time to implement this change, such that HSD/MAD should discuss delaying this requirement with CMS?

d. There have been some initial discussions with IHS and tribal healthcare providers on following some other states, in paying for pharmacy claims at a client OMB rate. Do IHS and tribal healthcare providers believe that New Mexico should propose this option to CMS?

Tribal Advice and Comments
Tribes and tribal health care providers may view proposed State Plan Amendment (SPA) 17-003 on the HSD webpage at http://www.hsd.state.nm.us/public-notices-proposed-rule-and-waiver-changes-and-opportunities-to-comment.aspx.

SPA 17-003 Covered Outpatient Drug Rule

A written copy of these proposed documents may be requested by contacting the HSD Medical Assistance Division (HSD/MAD) in Santa Fe at (505) 827-6252.

Important Dates
Following federal requirements, the effective date of these changes is April 1, 2017. If changes to the draft State Plan Amendment are required based upon tribal comments or as requested by CMS, any claims paid on or after April 1, 2017 will be adjusted retroactively to reflect the final approval by CMS.
HSD intends to file the State Plan amendment after the public comment period, but no later than April 20, 2017.

**OPPORTUNITY TO VIEW DOCUMENTS AND MAKE COMMENTS:** Medicaid providers, Medicaid recipients, and other interested parties are invited to make comments on this proposal.

**Written advice and comments must be received no later than 5:00 pm MST on Wednesday, April 19, 2017.** Please send your advice, comments or questions to the MAD Native American Liaison, Theresa Belanger, at (505) 827-3122 or by email to theresa.belanger@state.nm.us.

All comments and responses will be compiled and made available after April 15, 2017.

Sincerely,

Nancy Smith-Leslie
Director

cc: Kari Armijo, HSD/MAD Deputy Director
    Theresa Belanger, Native American Liaison, HSD/MAD
    HSD/MAD Centennial Care Bureau
    HSD/MAD Program Policy Bureau